

CLAIMS

1 1. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a material extending along a coiled path along the entire coiled body; and
5 a dispensable, biologically active agent associated with at least one of the coiled body
6 and the material, said dispensable agent being dispensable into a hollow body structure of a
7 patient.

1 2. The prosthesis according to claim 1 further comprising a delay-release material associated
2 with the dispensable agent to delay the release of the dispensable agent into the hollow body
3 structure.

1 3. The prosthesis according to claim 2 wherein the delay-release material comprises a
2 biodegradable, delay-release layer.

1 4. The prosthesis according to claim 1 wherein the dispensable agent is microencapsulated
2 using a biodegradable encapsulation material so as to delay migration of said drug from said
3 prosthesis.

1 5. The prosthesis according to claim 1 further comprising removing a protective layer from
2 said coiled body and material there with so that when removed, said dispensable agent may
3 migrate from said prosthesis.

1 6. The prosthesis according to claim 5 wherein the protective layer comprises a
2 biodegradable material so that said protective layer is removed when it biodegrades.

1 7. The prosthesis according to claim 5 wherein the protective layer comprises a sheath which
2 can be pulled off the coiled body and material there with to remove the protective layer
3 therefrom.

1 8. The prosthesis according to claim 1 wherein said body has longitudinally extending side
2 members and cross members connecting said side members.

1 9. The prosthesis according to claim 1 wherein said body is made of metal.

1 10. The prosthesis according to claim 1 wherein said prosthesis comprises spaced apart turns
2 defining gaps therebetween when in the radially-expanded state.

1 11. The prosthesis according to claim 1 wherein the prosthesis comprises turns, adjacent
2 ones of said turns touching one another when in the radially-expanded state.

1 12. The prosthesis according to claim 1 wherein the material comprises a coiled sleeve of
2 material having inner and outer surfaces, said inner surface defining a sleeve interior
3 containing the entire coiled body.

1 13. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: on the outer surface of the material, the outer surface
3 being placeable against the hollow body structure when the body is in the radially-expanded
4 state so the material may be located at and dispensable from only locations of intimate
5 contact with the hollow body structure.

1 14. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: incorporated into the material to create an agent/material
3 matrix.

1 15. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: on the inner surface of the material.

1 16. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: within the sleeve interior.

1 17. The prosthesis according to claim 1 wherein the material has a radially-inwardly facing
2 inner surface and a radially-outwardly facing outer surface, and material surrounding the
3 body with said inner surface adjacent to the body and the outer surface placeable against the
4 hollow body structure when the body is in the radially-expanded state.

1 18. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from the outer surface of the material so to be located at and dispensable from only locations
3 of intimate contact with the hollow body structure.

1 19. The prosthesis according to claim 1 further comprising first and second dispensable
2 agents.

1 20. The prosthesis according to claim 19 wherein said first agent is layered on top of said
2 second agent.

1 21. The prosthesis according to claim 19 wherein said first agent is dispensable prior to the
2 start of dispensing of the second agent.

1 22. The prosthesis according to claim 19 wherein at least half of said first agent is
2 dispensable prior to the start of dispensing of the second agent.

1 23. The prosthesis according to claim 1 wherein said material is a porous material.

1 24. The prosthesis according to claim 23 wherein said porous material comprises porous
2 PTFE.

1 25. The prosthesis according to claim 23 wherein said porous material has an inner surface
2 which is substantially impervious to the passage of blood therethrough.

1 26. The prosthesis according to claim 1 wherein the dispensable agent is selected from the
2 group comprising: anti-inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-
3 proliferative drugs, apoptosis-inducing drug, light activated drug, and biological materials.

1 27. The prosthesis according to claim 1 wherein the dispensable agent comprises an anti-
2 restenotic agent.

1 28. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent on said outer surface of the material, said
7 dispensable agent being dispensable into a hollow body structure of a patient.

1 29. The prosthesis according to claim 28 wherein the dispensable agent comprises an anti-
2 restenotic agent.

1 30. The prosthesis according to claim 28 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 31. The prosthesis according to claim 28 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 32. The prosthesis according to claim 28 wherein said material comprises porous PTFE.

1 33. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent incorporated into the material to create an
7 agent/material matrix, said dispensable agent being dispensable into a hollow body structure
8 of a patient.

1 34. The prosthesis according to claim 33 wherein the dispensable agent comprises an anti-
2 restenotic agent.

1 35. The prosthesis according to claim 33 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 36. The prosthesis according to claim 33 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 37. The prosthesis according to claim 33 wherein said material comprises porous PTFE.

1 38. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent on said inner surface of the material or within
7 the sleeve interior, said dispensable agent being dispensable into a hollow body structure of a
8 patient.

1 39. The prosthesis according to claim 38 wherein the dispensable agent comprises an anti-
2 restenotic agent.

1 40. The prosthesis according to claim 38 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 41. The prosthesis according to claim 38 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 42. The prosthesis according to claim 38 wherein said material comprises porous PTFE.

1 43. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a material extending along a
6 coiled path along the entire coiled body, and a dispensable, biologically active agent
7 associated with at least one of the coiled body and the material;

8 radially expanding the prosthesis from the radially-contracted state to a radially-
9 expanded state so to press the prosthesis against a wall of the hollow body structure; and
10 releasing the agent into the hollow body structure.

1 44. The method according to claim 43 further comprising selecting a prosthesis comprising a
2 coiled body having longitudinally extending side members and cross members connecting
3 said side members.

1 45. The method according to claim 43 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 46. The method according to claim 43 wherein the radially expanding step is carried out with
2 a prosthesis comprising turns which touch one another when in the radially-expanded state.

1 47. The method according to claim 43 further comprising selecting a prosthesis in which the
2 material comprises a coiled sleeve of material, said coiled sleeve of material having inner and
3 outer surfaces, said inner surface defining a sleeve interior containing the entire coiled body.

1 48. The method according to claim 43 further comprising selecting a prosthesis in which the
2 agent comprises first and second dispensable agents.

1 49. The method according to claim 48 further comprising selecting a prosthesis having said
2 first agent layered on top of said second agent.

1 50. The method according to claim 48 wherein the releasing step is carried out so that at least
2 a portion of said first agent is released prior to the start of release of the second agent.

1 51. The method according to claim 48 wherein the controllably releasing step is carried out
2 so that at least half of said first agent is released prior to the start of release of the second
3 agent.

1 52. The method according to claim 43 further comprising selecting a prosthesis comprising
2 porous material as said material.

1 53. The method according to claim 52 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material comprising ePTFE.

1 54. The method according to claim 52 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material has a surface which is substantially impervious to the
3 passage of blood therethrough.

1 55. The method according to claim 43 further comprising selecting a prosthesis having a
2 delay-release material associated with the dispensable agent.

1 56. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable, delay-release
3 material.

1 57. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a delay-release layer covering the
3 dispensable agent.

1 58. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material is a component of a matrix of the dispensable
3 agent and the delay-release material.

1 59. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable polymer.

1 60. The method according to claim 55 wherein the delay-release material comprises a
2 protective layer, and further comprising removing the protective layer from the coiled body
3 and material therewith thereby exposing the coiled body and material therewith.

1 61. The method according to claim 43 further comprising selecting a prosthesis comprising a
2 dispensable agent selected from the group comprising: anti-inflammatory drugs, anti-
3 thrombotic/anti-platelet drugs, anti-proliferative drugs, apoptosis-inducing drug, light
4 activated drug, and biological materials.

1 62. The method according to claim 43 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 63. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:
3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material
6 extending along a coiled path, the coiled sleeve of material comprising inner and outer
7 surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a
8 dispensable, biologically active agent on the outer surface of the material;
9 radially expanding the prosthesis from the radially-contracted state to a radially-
10 expanded state so to press the prosthesis against the wall; and
11 releasing the agent from the outer surface of the material and into the hollow body
12 structure.

1 64. The method according to claim 63 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 65. The method according to claim 63 wherein the releasing step comprises temporally
2 controllably releasing the agent into the hollow body structure.

1 66. The method according to claim 63 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 67. The method according to claim 63 further comprising selecting a prosthesis comprising
2 porous PTFE as said material.

1 68. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material
6 extending along a coiled path, the coiled sleeve of material comprising inner and outer
7 surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a
8 dispensable, biologically active agent incorporated into the material to create an
9 agent/material matrix;

10 radially expanding the prosthesis from the radially-contracted state to a radially-
11 expanded state so to press the prosthesis against the wall; and

12 releasing the agent from the agent/material matrix and into the hollow body structure.

1 69. The method according to claim 68 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 70. The method according to claim 68 wherein the releasing step comprises temporally
2 controllably releasing the agent into the hollow body structure.

1 71. The method according to claim 68 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 72. The method according to claim 68 further comprising selecting a prosthesis comprising
2 porous PTFE as said material.

1 73. The method according to claim 68 further comprising selecting a prosthesis in which the
2 material comprises a coiled sleeve of material, said coiled sleeve of material having inner and
3 outer surfaces, said inner surface opposite said coiled body, said inner surface defining a
4 sleeve interior containing the entire coiled body.

1 74. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material

6 extending along a coiled path, the coiled sleeve of material comprising inner and outer
7 surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a
8 dispensable, biologically active agent on the inner surface of the material or within the sleeve
9 interior;

10 radially expanding the prosthesis from the radially-contracted state to a radially-
11 expanded state so to press the prosthesis against the wall; and

12 releasing the agent from the inner surface of the material and into the hollow body
13 structure.

1 75. The method according to claim 74 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 76. The method according to claim 74 wherein the releasing step comprises temporally
2 controllably releasing the agent into the hollow body structure.

1 77. The method according to claim 74 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 78. The method according to claim 74 further comprising selecting a prosthesis comprising
2 porous PTFE as said material.

1 79. A method for making a prosthesis for use at a target site within a hollow body structure
2 of a patient comprising:

3 determining at least one therapy for a patient;
4 selecting a prosthesis suitable for said at least one therapy, said prosthesis comprising
5 a coiled body having radially-extending openings formed therethrough, a material extending
6 along a coiled path along the entire coiled body, and first and second dispensable,
7 biologically active agents for said therapy, said first and second agents being associated with
8 at least one of said coiled body and said material; and

9 said selecting step being carried out so that at least some of said first agent is
10 releasable at a target site within a hollow body structure of a patient prior to the start of the
11 release of the second agent at the target site.

1 80. The method according to claim 79 wherein the selecting step is carried out by selecting a
2 prosthesis with a porous material as said material.

1 81. The method according to claim 80 wherein the selecting step is carried out with the
2 porous material comprising ePTFE.

1 82. The method according to claim 80 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material having a surface which is substantially impervious to the
3 passage of blood therethrough.

1 83. The method according to claim 79 wherein the selecting step is carried out by selecting a
2 prosthesis having said first agent layered on top of said second agent.

1 84. The method according to claim 79 wherein said selecting step is carried out so that
2 said first agent is releasable over a first period and said second agent is releasable over a
3 second period, said first and second periods at least partially overlapping.

1 85. The method according to claim 79 wherein the selecting step is carried out by selecting a
2 prosthesis having a delay-release material associated with at least one of the first and second
3 agents.

1 86. The method according to claim 85 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable, delay-release layer.

1 87. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis comprising dispensable agents selected from the group comprising: anti-
3 inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-proliferative drugs, apoptosis-
4 inducing drug, light activated drug, and biological materials.

1 88. The method according to claim 79 further comprising selecting anti-restenotic agents as
2 the dispensable agents.

1 89. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis in which the material comprises a coiled sleeve of material, said coiled sleeve of
3 material having inner and outer surfaces, said inner surface defining a sleeve interior
4 containing the entire coiled body, the selecting step being carried out with the agents being
5 releasable from at least one of the following locations: the outer surface of the material,
6 incorporated into the material to create an agent/material matrix, on the inner surface of the
7 material, and within the sleeve interior.

1 90. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 91. A method for making a prosthesis for use at a target site within a hollow body structure
2 of a patient comprising:

3 placing a length of a material in contact with a mixture of a carrier and a dispensable,
4 biologically active agent;

5 removing at least a substantial portion of the carrier from the mixture leaving said
6 agent in contact with the material to create an agent-laden material;

7 combining the agent-laden material with a radially-expandable stent to create a
8 prosthesis suitable for use within a hollow body structure of a patient.

1 92. The method according to claim 91 wherein the placing step is carried out using a porous
2 material as the material.

1 93. The method according to claim 92 wherein the placing step is carried out with the porous
2 material comprising ePTFE.

1 94. The method according to claim 92 further comprising selecting a length of porous sleeve
2 material as said porous material, said porous sleeve material comprising inner and outer
3 surfaces, said inner surface defining a sleeve interior containing the entire stent following the
4 combining step.

1 95. The method according to claim 94 wherein said placing step is carried out by placing
2 said mixture into said sleeve interior.

1 96. The method according to claim 95 wherein the selecting step is carried out using a sleeve
2 material having open ends, and the placing step comprises at least temporarily sealing one
3 said open end.

1 97. The method according to claim 91 wherein said removing step is carried out by draining
2 away excess amounts of said mixture and then at least partially drying said length of material.

1 98. The method according to claim 91 further comprising selecting an agent from the group
2 comprising: anti-inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-proliferative
3 drugs, apoptosis-inducing drug, light activated drug, and biological materials.

1 99. The method according to claim 91 further comprising selecting an anti-restenotic agent
2 as the biologically active agent.

1 100. The method according to claim 91 wherein the combining step is carried out with a
2 prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

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